

Remarks

Claims 1-11, 16-18, 21-25, 27-31, 55-57, 61-63, and 66-71 are pending and under consideration in this application.

Claims 1, 31, 55, 67 and 71 are amended herein to recite “such that said first filter layer retards the flow of cellular debris.” Support for these amendments can be found, *inter alia*, in paragraph [0009] of the specification. No new matter is added by these amendments.

Claim Rejections Under 35 U.S.C. § 102(b)

Claims 67-71 stand rejected under 35 U.S.C. § 102(b) as being anticipated by Nieuwkerk *et al.* (U.S. Patent No. 5,438,128) (Nieuwkerk). (Office Action, page 3.) Applicants respectfully disagree.

An anticipation rejection under 35 USC § 102 requires a showing that each limitation of a claim is found in a single reference, practice, or device. *See Kalman v. Kimberly Clark Corp.*, 713 F.2d 760, 771 (Fed. Cir. 1983), *cert. denied*, 465 U.S. 1026 (1984). The test for anticipation is one of strict identity. *Trintec Industries, Inc. v. Top-U.S.A. Corp.*, 63 U.S.P.Q.2d 1597 (Fed. Cir. 2002). “Though anticipation is the epitome of obviousness, [they] are separate and distinct concepts” *See Jones v. Hardy*, 727 F.2d 1524, 1529, 220 USPQ 1021, 1025 (Fed. Cir. 1984).

The Examiner asserts Nieuwkerk teaches a method for convenient and rapid isolation of nucleic acids which comprise membranes stacked one on top of the other to form a column having a short bed depth. (Office Action, page 3.) Applicants have amended independent claims 67 and 71 to recite “that said first filter layer retards the flow of cellular debris” to more clearly define the subject matter of the claims. The method disclosed by Nieuwkerk uses multiple stacked membranes but there is no disclosure that the first membrane in the stack retards the flow of cellular debris. To the contrary, Nieuwkerk discloses that “plasmid DNA can be isolated from a crude bacterial lysate in a stepwise manner by first removing biomolecules and cellular contaminant material that do not bind to the ion exchange membranes.” (Nieuwkerk, column 7, lines 8-12.) Further, in the examples, Nieuwkerk discloses that cellular debris are removed by precipitation with potassium acetate

yielding a “clear supernatant free of cellular particulate.” (Nieuwkerk, column 8, lines 36-48.) Thus, Nieuwkerk does not disclose a method where a “first filter layer retards the flow of cellular debris” and therefore does not anticipate the pending claims.

In view of the above Applicants respectfully request reconsideration and withdrawal of the rejections under 35 U.S.C. § 102(b).

Claim Rejections Under 35 U.S.C. § 103

Claims 1-11, 16-18, 21-25, 27-31, 55-57, 61-63 and 66 stand rejected under 35 U.S.C. 103(a) as being unpatentable over Jones (WO 95/02049) in view of Nieuwkerk. (Office Action, page 6.) Applicants respectfully disagree.

The Examiner asserts that Jones teaches a method of separating biological compounds from cells by a filtration apparatus using two filters with increasing pore size in the direction of sample flow (Office Action, page 6). The Examiner also alleges that Jones teaches the method of purifying nucleic acid from cells that comprises lysing a cell suspension to form a cell lysate contacting nucleic acid and applying the cell lysate to filter to remove unwanted cells and cell debris.

Applicants assert that the disclosure of Jones significantly differs from the instant claims. Jones does not teach or disclose that the filter and the solid phase matrix are housed within the “same” housing chamber or column. In fact, Jones clearly teaches a first and a second chamber that separately house the filter or filter matrix (Figure 5 and page 8, paragraph 2, WO 95/02049). Applicants particularly note that Jones passes the target molecule (e.g.: DNA) through the first filter, but NOT through the second filter. That is, Jones binds the target molecule to the second matrix (instead of passing it through like the instantly claimed invention) and it is further noted that the methods taught by Jones necessarily include an elution step.

Moreover, Jones does not teach or disclose “multilayer filter beds” or “a filtration apparatus assembled into a cartridge housing.” As discussed above, Nieuwkerk does not remedy the deficiencies of Jones. Therefore, all of the elements of the present claims are not taught or suggested by the cited art.

In view of the above, Applicants respectfully request reconsideration and withdrawal of the rejections under 35 U.S.C. 103(a).

Conclusion

All of the stated grounds of rejection have been properly traversed, accommodated, or rendered moot. Applicants therefore respectfully request that the Examiner reconsider and withdraw all presently outstanding rejections. Applicants believe that a full and complete reply has been made to the outstanding Office Action and, as such, the present application is in condition for allowance. If the Examiner believes, for any reason, that personal communication will expedite prosecution of this application, the Examiner is invited to telephone the undersigned.

Prompt and favorable consideration of this Amendment and Reply is respectfully requested.

Respectfully submitted,

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